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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/718,758 | 11/21/2003 | Karen Peilstocker | CH-7906/LeA 36,417 | 1442 |
| 34947 | 7590 | 08/13/2004 | EXAMINER | |
| LANXESS CORPORATION PATENT DEPARTMENT/ BLDG 14 100 BAYER ROAD PITTSBURGH, PA 15205-9741 | | | WITHERSPOON, SIKARL A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1621 | |

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/718,758

Applicant(s)

PEILSTOCKER ET AL.

Examiner

Sikarl A. Witherspoon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-20 and 22 is/are allowed.
- 6) ☒ Claim(s) 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claim is drawn to a process for preparing active ingredients from medicaments comprising providing compounds according to claim 15; however, the specification does not provide any teaching as to which compounds according to claim 15 can be used for preparing such active ingredients for medicaments, what are the medicaments used for, etc. Since the specification does not provide any guidance in the preparation of the active ingredients for medicaments as per the instant claim, it would constitute undue experimentation to determine which compounds encompassed by the generic formula of claim 15 can be used to prepare active ingredients for medicaments; what are the medicaments useful for treating, and what are the proper formulations of the compounds of claim 15 that would show efficacy as an active ingredient for a medicament, etc.

There are eight (8) factors considered by the Federal Circuit in the determination of undue experimentation, *In re Wands*, 8 USPQ2d 1400 (1988). These factors are: the

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nature of the invention, the breadth of the claims, the state of the prior art, the predictability or unpredictability of the art, the amount of direction or guidance presented, the presence or absence of working examples, the relative skill of those in the art, and the quantity of experimentation necessary. The examiner will discuss these factors as they apply to the instant invention.

Nature of the invention. As stated above, the instant claim is drawn to the preparation of active ingredients for medicaments, by providing compounds according to claim 15 of the present invention.

Breadth of claims. The rejected claim is broad, in that it is drawn to the preparation of active ingredients for medicaments by *providing* compounds of claim 15, in which the generic compound of claim 15 encompasses many different compounds. Furthermore, the term “medicaments”, in effect, encompasses any and every known formulation that may be used as a medicament, that is, to treat some type of condition.

State of prior art. Fluorinated benzaldehydes can be used as the active ingredient in a formulation used to treat such maladies as cardiovascular disorders and diseases.

Predictability or unpredictability of the art. There are many possible species that are encompassed by the generic structure recited in claim 15, and as such, it would not be reasonable for a person of ordinary skill in the art to expect that all compounds encompassed by the generic structure in claim 15 would be efficacious as an active ingredient for a medicament, especially without any guidance on what the medicaments are used for.

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Amount of guidance present. The instant specification provides no guidance as to how active ingredients for medicaments are *prepared* by simply *providing* compounds according to claim 15.

Presence of working examples. There are no working examples related to the preparation of active ingredients for medicaments in the instant specification.

Quantity of experimentation necessary. The quantity of experimentation that would be required of a person having ordinary skill could potentially be infinite without further guidance. As stated above, many different species are possible from the generic compound recited in claim 15. One would have ascertain which of the many possible species could be used to prepare an active ingredient for a medicament, but first, since there is no guidance in the specification, a person of ordinary skill would have to ascertain what types of conditions can be treated by medicaments comprising compounds of instant claim 15 as an active ingredient. Then, further experiment to find the species that would be efficacious in the preparation of an active ingredient for a medicament. Furthermore, it would confound a person having ordinary skill in the art as to how merely “providing” compounds constitutes “preparing” active ingredients for medicaments. Therefore, a person of ordinary skill would have to experiment to find the proper sequence of steps that would result in the preparation of an active ingredient for a medicament. All of these elements taken into consideration make the experimentation unduly burdensome.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claim is drawn to a process for preparing active ingredients for medicaments, however, the claim does not provide any steps by which the process occurs, and does not recite the type(s) of medicament comprising the active ingredient. Furthermore, it is unclear how merely *providing* compounds constitutes the *preparation* of something.

Allowable Subject Matter

The following is a statement of reasons for the indication of allowable subject matter: claims 1-14 are drawn to a process for preparing compounds of formula (I). The closest prior art of record fails to teach or fairly suggest a process wherein a phenol of formula (II) is reacted with urotropin, in the presence of an acid to form compounds of formula (I), as claimed herein.

Claims 15-20 are drawn to compounds that are neither taught nor suggested by the closest prior art of record. Claim 22 is drawn to a process for treating cardiovascular disorders and diseases by administering medicaments containing active ingredients based on compounds of claim 15, compounds not taught or suggested by

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the closest prior art of record, and as such, claim 22 is considered unobvious in view of the closest prior art or record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sikarl A. Witherspoon whose telephone number is 571-272-0649. The examiner can normally be reached on M-F 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 8/10/04

Sikarl A. Witherspoon
Patent Examiner
Technology Center 1600